BARNES & THORNBURG LLP

11 South Meridian Street
Indianapolis, Indiana 46204
(317) 236-1313
(317) 231-7433 Fax

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit:	3773
Confirmation No.:	5422
Application No.:	10/758,372
Invention:	SOFT TISSUE LOCKING DEVICE
Inventor:	Herbert E. Schwartz et al.
Filed:	January 15, 2004
Attorney Docket:	26502-73682
Examiner:	Woo, Julian W.

ELECTRONICALLY SUBMITTED: March 15, 2010

APPEAL BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants electronically submit this Appeal Brief in support of the appeal filed on January 13, 2010 from the rejection of claims 1-4 and 6-17 set forth in the Final Office Action dated October 13, 2009 (hereinafter "Final Office Action"). Appellants hereby authorize the Director to charge the fee for filing this Appeal Brief ($540.00), as well as any additional fees, or credit any overpayments, to Deposit Account No. 10-0435, with reference to our file number 26502-73682.

REAL PARTY IN INTEREST

The real party in interest is DePuy Orthopaedics, Inc., a Johnson & Johnson Company.

RELATED APPEALS AND INTERFERENCES

Appellants know of no other related applications that have been appealed to the Board of Patent Appeals and Interferences.

STATUS OF CLAIMS

Claims 1-4 and 6-17 are pending in the above-identified application.

Claim 5 was canceled in the Response to Office Action dated February 6, 2006.

Each of claims 1-4 and 6-17 were rejected in the Office Action dated October 13, 2009.

Claims 1-4 and 6-17 were appealed in the Notice of Appeal dated January 13, 2010.

STATUS OF AMENDMENTS

Appellants have made no amendments to the claims subsequent to the October 13, 2009 Final Office Action.

SUMMARY OF CLAIMED SUBJECT MATTER

Independent Claim 1:

Independent claim 1 recites a device for repairing a defect in a soft tissue including a first anchor (20) for engaging a first surface of the soft tissue on a first side of the defect. The first anchor (20) has a locking mechanism (46) and a cannula (22) defined therein that includes a first lumen. The first anchor (20) is shaped to seat below the first surface of the soft tissue. The device also includes a second anchor (80) for engaging against a second side of the soft tissue on a second side of the defect; and a suture (40) adjustably connecting the second anchor (80) to the first anchor (20). Tension on the suture (40) pulls the second anchor (80) toward the first anchor (20) through a continuous range of distances, thereby pulling the first and second sides of the defect together to close the defect. The locking mechanism (46) locks the suture (40) in place at any point along the suture (40).

The second anchor (80) has a hole (82) and the suture (40) connects the first anchor (20) to the second anchor (80) by passing through the first lumen of the cannula (22) of the first anchor (20) while traveling in a first direction, by passing through the hole (82) of the second anchor (80), and by returning through the first lumen of the cannula (22) of the first anchor (20) while traveling in a second and opposite direction.

The apparatus of claim 1 is illustratively shown in FIGS. 1-4 and is described in the passages of the written description page 5, line 1 through page 6, line 15.

Independent Claim 6:

Independent claim 6 recites a device for repairing a defect in a soft tissue including a first anchor (20) for engaging a first surface of the soft tissue on a first side of the defect. The first anchor (20) has a locking mechanism (46) and a cannula (22) defined therein including a first lumen. The first anchor (20) is shaped to seat below the first surface of the soft tissue. The device also includes second anchor (80) for engaging against a second surface of the soft tissue on a second side of the defect, and a suture (40) adjustably connecting the second anchor (80) to the first anchor (20).

The second anchor (80) has a hole (82) therethrough, and the suture (40) connects the first anchor (20) to the second anchor (80) by passing through the first lumen of the cannula (22) of the first anchor (20) while traveling in a first direction, by passing through the hole of the second anchor (80), and by returning through the first lumen of the cannula (22) of the first anchor (20) while traveling in a second and opposite direction and wherein tension on the suture (40) pulls the second anchor (80) toward the first anchor (20), thereby pulling the first and second sides of the defect together to close the defect, and the locking mechanism (46) locks the suture (40) in place.

The apparatus of claim 6 is illustratively shown in FIGS. 1-4 and is described in the passages of the written description page 5, line 1 through page 6, line 15.

Independent Claim 10:

Independent claim 10 recites a device for repairing a defect in a soft tissue including a first anchor (20) for engaging a first surface of the soft tissue on a first side of the

defect. The first anchor (20) has a locking mechanism (46) and a single lumen defined therethough. The first anchor (20) having a frustoconical end shaped to bury into and seat below the first surface of the soft tissue. The device includes a second anchor (80) for engaging a second surface of the soft tissue on a second side of the defect. The second anchor (80) includes at least one hole (82).

The device includes a suture (40) coupled to the first anchor (20) and the second anchor (80). The suture (40) passes through the lumen of the first anchor (20), passes through the at least one hole (82) of the second anchor (80), and returns through the lumen of the first anchor (20). Tension on the suture (40) pulls the second anchor (80) toward the first anchor (20) such that the first and second sides of the defect are pulled together and the locking mechanism (46) locks the suture (40) in place.

The apparatus of claim 10 is illustratively shown in FIGS. 1-4 and is described in the passages of the written description page 5, line 1 through page 6, line 15.

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Appellants present to following grounds of rejection for the Board to review:

(I) the rejection of claims 1-4 and 6-9 under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,010,525 filed by Bonutti (hereinafter Bonutti); and

(II) the rejection of claims 10-17 under 35 U.S.C. § 103(a) as being unpatentable over Bonutti in view of U.S. Patent No. 5,391,173 issued to Wilk.

ARGUMENT

I. APPELLANTS URGE THE BOARD TO REVERSE THE FIRST GROUND OF REJECTION.

Appellants will argue the claims within the first ground of rejection in the following group:

Group A – claims 1, 4, 6, & 9;

Group B – claims 2 & 7; and

Group C – claims 3 & 8.

A. CLAIMS 1, 4, 6, & 9 ARE NOT ANTICIPATED BY BONUTTI.

Appellants assert the 35 U.S.C. § 102(e) rejection of claims 1, 4, 6, and 9 is improper because Bonutti fails to disclose each and every element of the claimed invention. Indeed, Bonutti fails to disclose a first anchor that is, amongst other things, "shaped to seat below the first surface of the soft tissue." On page 2 of the Final Office Action, the rejection asserts:

> Bonutti et al disclose, at least in figures 26-28 and col. 26, line 63 to col. 28, line 24; a device including *a first anchor (540)* having a locking mechanism (542) configured to grip and hold or lock a suture at any point along the suture; and a cannula (544) including a first lumen (578), *the first anchor being shaped to seat below the first surface of soft tissue (54)* or is capable of seating below the first surface of a meniscus, whereby proper seating of the device closes a defect without interfering with joint articulation.

(emphasis added). Contrary to the rejection's assertion, Bonutti simply does not disclose a device "shaped to seat below the first surface of the soft tissue" under the broadest reasonable interpretation of that phrase. As such, Bonutti fails to anticipate the claimed invention.

Verdegaal Bros. v. Union Oil Co. of California emphasizes that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). In addition, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). More recently, the Federal Circuit stated that "unless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. §

102." *Net MoneyIN v. Verisign*, 545 F.3d 1359, 88 USPQ2d 1751, 1759 (Fed. Cir. 2008). In this case, Bonutti does not expressly teach that the suture retainer 540 is "shaped to seat below the first surface of the soft tissue" and, in fact, teaches just the opposite: "[t]he bottom side surface 564 of the base portion 542 [of suture retainer 540 is] pressed *against an upper side surface 98* of the body tissue 54." *See* Bonutti, at col. 28, lines 21-23 (emphasis added).

As shown in FIG. 29, the suture retainer 540 of Bonutti is positioned on and pressed against the surface 98 of the body tissue 54. Indeed, Bonutti clearly teaches a structure designed be *positioned on* the largest possible surface area of the body tissue 54. Such a structure is the very antithesis of an anchor "shaped to seat *below* the first surface of the soft tissue." As Bonutti explains at col. 1, lines 24-29, it is "desirable to be certain that the suture applies a desired amount of force to the body tissue when the suture is secured. *The overall force transmitting capability of the suture should be maximized without concentrating the force at a small area on the body tissue*" (emphasis added). To accomplish that objective, Bonutti discloses that the suture retainer 540 has a "bottom side surface 564" that is "pressed against an upper side surface 98 of the body tissue 54 in the manner illustrated in FIG. 26." *See* Bonutti, at col. 28, lines 21-23. Bonutti then describes that "[t]he *flat circular* bottom side surface 564 of the flange 548 transmits force from the suture 52 *to a relatively large area* ***on the surface 98*** *of the body tissue 54*." *Id.* at col. 28, lines 24-27. In other words, rather than "being shaped to seat *below* the first surface of the soft tissue," the suture retainer 540 is designed specifically to seat not just *on* the outer surface of the soft tissue but *on the largest possible area of the outer surface of the soft tissue* so as to maximize the overall force transmitting capability of the suture. Bonutti's device is therefore expressly designed to be *seated on* the outer surface of the soft tissue, *not below the surface* of the soft tissue as required by the claims.

Despite this clear teaching, the rejection proposes that if the orientation of the soft tissue shown in FIG. 29 were turned upside down, the suture retainer 540 would somehow fulfill the requirement of "being shaped to seat below the first surface of the soft tissue" as required by the claims. On page 4 of the Final Office Action, the rejection asserts:

> *[T]he recitation that an element is "shaped" to perform a function only requires the ability to so perform.* And given the broadest reasonable interpretation of the phrase "below the first surface of soft tissue," *Bonutti's first anchor is indeed capable of being seated or positioned below soft tissue, if, for example, the orientation of the soft tissue, as shown in figure 26, is turned upside down, such that first anchor 540 is deemed to be "below" the first surface of soft tissue.* Bonutti's recitation of the anchor being "pressed against upper side surface 98 of

> body tissue" is only referring to an instance where the orientation of the body tissue as shown in figure 26 results in the suture retainer being above the first surface of tissue. *Certainly, a patient and his or her soft tissue may be oriented in various positions, and Bonutti's first anchor is configured to be oriented and fastened in place according to the position of the soft tissue – a position that may be deemed "below the first surface of tissue."*

(emphasis added). As highlighted above, the rejection asserts that "the recitation that an element is 'shaped' to perform a function only requires the ability to so perform," but the rejection cites no authority for this test.

Even assuming *arguendo* that the rejection's "test" is the correct one, the rejection is based on a misapplication of the broadest reasonable interpretation standard. In developing a rejection under Section 102, the Patent and Trademark Office is required to determine the scope of the claims, but it cannot construe the claim terms in a manner that is contrary the language of the claims and the interpretative guidance afforded by the applicants' specification. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312, 75 USPQ2d 1321, 1329 (Fed. Cir. 2005). When determining the scope of the claims in patent applications, the Patent and Trademark Office is required to give the "claims their broadest reasonable construction in light of the specification as it would be interpreted by one of ordinary skill in the art." *Id.* (internal citation omitted). In doing so, the broadest reasonable interpretation of a claim limitation must be developed in light interpretative guidance provided in the applicants' specification. As the Federal Circuit declared in the *In re Morris* decision,

> Since it would be unreasonable for the PTO to ignore *any interpretive guidance afforded by the applicant's written description*, either phrasing connotes the same notion: as an initial matter, the PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification.

127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997) (emphasis added); *see also* MPEP § 2111 (citing the *Morris* decision as an example to examiners). Once that standard is properly applied, Bonutti clearly fails disclose a first anchor shaped to seat below the soft tissue.

Even if FIG. 26 of Bonutti were turned upside down, the suture retainer 540 would still be *positioned on* the outer surface of the soft tissue and would not fulfill the requirement of "being shaped to seat below the first surface of the soft tissue." Indeed, merely reversing the orientation of the suture retainer 540 changes nothing – the suture retainer 540 is still not seated

below the soft tissue but rather is *seated on the largest possible area of the outer surface of the soft tissue*. The rejection's assertion to the contrary simply defies the understanding of a person of ordinary skill.

Indeed, *by the rejection's logic, a BAND-AID® bandage applied to the sole of a person's foot would satisfy the claim when the person is standing on the foot.* Yet by that same logic, the BAND-AID® bandage would not be seated below the soft tissue if the person were standing on his head. Such a result is nonsensical and certainly falls well beyond any reasonable interpretation of the claims. Even when the BAND-AID® bandage is positioned *under* the foot, the bandage is still *on, not below,* the foot surface. As the term is used in the claims and in accordance with the understanding of one of ordinary skill, a position "below" the soft tissue clearly indicates a *subcutaneous* position. Nothing in Appellants' specification or within the common understanding of one skilled in the art would lead a person of ordinary skill to find that a structure shaped to be *seated on* a surface and *in contact with the largest possible area of* that surface is a structure shaped to be positioned below that surface.

Regardless of the orientation of the body tissue, *i.e., whether or not the patient is right-side-up or up-side down as proposed by the rejection*, the suture retainer 540 of Bonutti is shaped to be *seated on* an outer surface and is not shaped to be *seated below the surface* as required by the claims. Bonutti simply does not disclose a device "shaped to seat below the first surface of the soft tissue" under the broadest reasonable interpretation of that phrase. Because Bonutti does not disclose each and every element of claims 1, 4, 6, and 9, Bonutti cannot anticipate those claims under Section 102. Appellants therefore ask the Board to overrule the rejection of claims 1, 4, 6, and 9.

B. CLAIMS 2 & 7 ARE NOT ANTICIPATED BY BONUTTI.

Appellants assert the 35 U.S.C. § 102(e) rejection of claims 2 and 7 is improper because Bonutti fails to disclose each and every limitation of claims 2 and 7. Appellants fully incorporate into this section the legal authorities and arguments put forth in Section I.A above regarding the Section 102(e) rejection of claims 1, 4, 6, and 9. As set forth in Section I.A above, the suture retainer 540 of Bonutti is shaped to be *seated on* a surface and is not shaped to be *seated below the surface* as required by the claims. For that reason alone, Bonutti does not

disclose each and every element of claims 2 and 7 and therefore cannot anticipate those claims under Section 102.

The Board has recently reemphasized that "[t]he Examiner has the initial burden to set forth the basis for any rejection so as to put the patent applicant on notice of the reasons why the applicant is not entitled to a patent on the claim scope that he seeks – the so-called "*prima facie* case. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984) (the initial burden of proof is on the USPTO "to produce the factual basis for its rejection of an application under sections 102 and 103")." *Ex parte* Frye, Appeal No. 2009-006013, *slip op.* at 8 (Bd. Pat. App. & Int. Feb. 26, 2010). Here, claims 2 and 7 recite that "the soft tissue is a meniscus." The rejection asserts on page 2 of the Final Office Action that Bonutti discloses a "first anchor . . . capable of seating below the first surface of a *meniscus*;" however, the rejection has failed to put forth the factual basis necessary to support that assertion.

Indeed, the term "meniscus" simply does not appear in Bonutti. Bonutti does not therefore *expressly* disclose that an anchor may be used to engage a first surface of a meniscus on the first side of a defect. As such, the rejection's assertion on page 2 of the Final Office Action that Bonutti discloses a first anchor "capable of seating below the first surface of a meniscus" is not expressly supported by Bonutti's disclosure.

Nor has the rejection provided the analysis or evidence necessary to show that Bonutti's device is inherently capable of engaging a first surface of a meniscus. The Federal Circuit has said that anticipation by "[i]nherency, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991) (quoting *In re Oelrich*, 666 F.2d 578, 581 (C.C.P.A. 1981)) (emphasis added). The Examiner is required to provide extrinsic evidence that makes "clear that the missing descriptive matter is *necessarily* present." *Id.* at 1268 (emphasis added). As the Board itself has stated, "the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art." *Ex Parte Levy*, 17 USPQ 2d 1461, 1464 (BPAI 1990) (emphasis in original). Here, the rejection has failed to put forth any reasoning or evidence to show that the suture retainer 540 is *necessarily* capable of being used with meniscus.

As shown in FIG. 26, the suture retainer 540 appears to extend or protrude some distance above or away from the surface 98 of the soft tissue 54. Appellants' specification highlights on page 5, lines 20-21 that "a protruding anchor may interfere with joint articulation." It is simply unclear from Bonutti's disclosure whether or not the suture retainer 540 would interfere with joint articulation and therefore it is unclear whether Bonutti's device is suitable for use with meniscus. Perhaps, as the rejection suggests, Bonutti's device *might* be used with meniscus; yet given the fact that some protruding anchors interfere with joint articulation, it is equally possible that Bonutti's device *might not* be used with meniscus. Based on Bonutti's disclosure alone, it is impossible to say that Bonutti's device is *necessarily* capable of being used with meniscus, and the rejection has simply not set forth the required extrinsic evidence or reasoning that makes "clear that the missing descriptive matter is necessarily present." *See Continental Can Co.*, 948 F.2d at 1268. The rejection has therefore not established that Bonutti inherently discloses a first anchor capable of being used with meniscus.

Appellants therefore submit that the rejection has failed to show that Bonutti discloses expressly or inherently all of the elements of claims 2 and 7. The rejection has simply not provided the factual basis for its assertions. In that way, there is not even a *bona fide* dispute between the Appellants and the Examiner because the Examiner has not provided enough information to create one. Because the Examiner has not properly outlined the basis for his rejection, Appellants cannot properly evaluate the rejection and prepare a proper response with arguments and, if necessary, amendments. More importantly, the rejection has not shown that Bonutti anticipates claim 2 and 7, and Appellants respectfully urge the Board to overrule the rejection of those claims.

Moreover, given the Examiner's failure to articulate the basis of the rejection of claims 2 and 7, the Board's review represents the first meaningful substantive review of those claims. Should the Board decide that anything other than allowance of those claims is warranted, Appellants respectfully ask the Board to outline its position in a new ground of rejection so that Appellants can have an opportunity to adequately respond to what would be the first factually supported rejection of claims 2 and 7.

C. CLAIMS 3 & 8 ARE NOT ANTICIPATED BY BONUTTI.

Appellants assert the 35 U.S.C. § 102(e) rejection of claims 3 and 8 is improper because Bonutti fails to disclose each and every limitation of claims 3 and 8. Appellants fully incorporate into this section the legal authorities and arguments put forth in Section I.A above regarding the Section 102(e) rejection of claims 1, 4, 6, and 9 and in Section I.B above regarding the Section 102(e) rejection of claims 2 and 7. As set forth in Section I.A above, the suture retainer 540 of Bonutti is shaped to be *seated on* a surface and is not shaped to be *seated below the surface* as required by the claims. For that reason alone, Bonutti does not disclose each and every element of claims 3 and 8 and therefore cannot anticipate those claims under Section 102.

Claims 3 and 8 also recite that "proper seating of the device closes the defect without interfering with joint articulation." The rejection asserts on page 2 of the Final Office Action that Bonutti discloses that "proper seating of the device closes a defect without interfering with joint articulation;" however, the rejection has failed to put forth the factual basis necessary to support that assertion. Bonutti does not expressly disclose using the suture retainer 540 in connection with a knee joint and contains no discussion of joint articulation. As such, the rejection's assertion on page 2 of the Final Office Action that Bonutti discloses this limitation is not expressly supported by Bonutti's disclosure. Nor has the rejection provided the analysis or evidence necessary to show that Bonutti's device is inherently capable of properly seating such that the defect is closed without interfering with joint articulation.

The rejection has simply failed to put forth any reasoning or evidence to show that the suture retainer 540 is *necessarily* capable of seating such that the defect is closed without interfering with joint articulation. As shown in FIG. 26, the suture retainer 540 appears to extend or protrude some distance above or away from the surface 98 of the soft tissue 54. As discussed above, Appellants' specification highlights on page 5, lines 20-21 that "a protruding anchor may interfere with joint articulation." Perhaps, as the rejection suggests, proper seating of Bonutti's device *might* close a defect without interfering with joint articulation; yet given the fact that some protruding anchors interfere with joint articulation, it is equally possible that Bonutti's device *might not* close a defect without interfering with joint articulation. Based on Bonutti's disclosure alone, it is impossible to say that proper seating of Bonutti's device *necessarily* closes a defect without interfering with joint articulation, and the rejection has simply not set forth the

required extrinsic evidence or reasoning that makes "clear that the missing descriptive matter is necessarily present." *See Continental Can Co.*, 948 F.2d at 1268. The rejection has therefore not established that proper seating of Bonutti's device *inherently* closes a defect without interfering with joint articulation.

Appellants therefore submit that the rejection has failed to show that Bonutti discloses expressly or inherently all of the elements of claims 3 and 8. The rejection has simply not provided the factual basis for its assertions. Given this failure, the Examiner has not shown that Bonutti anticipates claims 3 and 8, and Appellants respectfully urge the Board to overrule the rejection of those claims.

Moreover, given the Examiner's failure to articulate the basis of the rejection of claims 3 and 8, the Board's review represents the first meaningful substantive review of those claims. Should the Board decide that anything other than allowance of those claims is warranted, Appellants respectfully ask the Board to outline its position in a new ground of rejection so that Appellants can have an opportunity to adequately respond to what would be the first factually supported rejection of claims 3 and 8.

II. APPELLANTS URGE THE BOARD TO REVERSE THE SECOND GROUND OF REJECTION.

Appellants fully incorporate into this section the legal authorities put forth in Section I above regarding the Section 102(e) rejection of claims 1-4 and 6-9. Appellants will argue the claims within the second ground of rejection in the following groups:

Group A – claims 10 & 13-17;

Group B – claim 11; and

Group C – claim 12.

A. CLAIMS 10 & 13-17 ARE NOT OBVIOUS OVER BONUTTI AND WILK

Appellants assert the 35 U.S.C. § 103(a) rejection of claims 10 and 13-17 is improper because the combination of Bonutti and Wilk fails to arrive at a device having "a first anchor for engaging a first surface of the soft tissue on a first side of the defect, . . . the first anchor having a frustoconical end shaped to bury into and seat below the first surface of the soft tissue." On pages 3 and 4 of the Final Office Action, the rejection asserts

> Bonutti et al. disclose the invention substantially as claimed. . . . However, Bonutti et al. do not disclose that the first anchor has a frustoconical end shaped to bury into and seat below the first surface of the soft tissue. Wilk teaches, at least in figures 1, 2C, and 2D and in col. 3, line 66 to col. 4, lines 39-50; a suture anchor (8) including an *external frustoconical shape*. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Wilk, to modify the first anchor of Bonutti et al. so that it has a frustoconical shape or end-shape. *Such a shape would provide a tapering surface for engagement of the anchor with a tool or by hand and allow sliding or pushing of the anchor along a suture and towards (or into) soft tissue*.

(emphasis added). On page 5 of the Final Office Action, the rejection further asserts:

> Wilk provides a teaching of a suture anchor (8) with a frustoconical end, *where the broad, flat circular bottom side of the anchor is engaged with soft tissue* (just like Bonutti's device). Contrary to the Applicant's suggestion, *the Examiner did not contend that the narrow, circular side of Wilk's frustoconical anchor is engaged with the soft tissue*. In short, there is no concentration of "force at a small area" if the suture retainer of Bonutti is modified to a frustoconical shape as taught by Wilk, *since Bonutti and Wilk teach the large, bottom sides of their anchors being engaged with tissue, where the anchors are configured to be "below" tissue (as defined above) and embedded (i.e., buried) in soft tissue*.

(emphasis added). As highlighted above, the rejection does not propose to modify the *tissue contacting* end of Bonutti's suture retainer 540 to have a frustoconical end. Instead, the rejection proposes to modify *the opposite, non-tissue contacting end* of the suture retainer 540 to have the frustoconical end. Appellants submit that such a modification does not arrive at the claimed invention because the resulting frustoconical end would not be "shaped to bury into and seat below the first surface of the soft tissue" as required by the claims.

The analysis of obviousness required under 35 U.S.C. § 103(a) must be resolved on the basis of the factual inquiries outlined in *Graham v. John Deere, Co.*, 383 U.S. 1, 148 USPQ 459 (1966); *see KSR v. Teleflex*, 127 S.Ct. 1727, 1740 (2007). The *Graham* Court stated that as part of any analysis under Section 103,

> the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.

148 USPQ at 467. The analysis of obviousness therefore requires an inquiry into the scope and content of the prior art and, more particularly, an inquiry into whether the prior art discloses all of the elements of the claimed invention. In at least that regard, the rejection of claims 10 and

13-17 is flawed because the rejection has not established that the proposed combination results in a device including all of the claimed limitations.

The rejection under Section 103, like the rejection of claims 1-4 and 6-9 under Section 102 discussed above, is premised on turning the orientation of the soft tissue shown in FIG. 29 of Bonutti upside down. As set forth in Section I.A above, even if FIG. 26 of Bonutti were turned upside down, the suture retainer 540 would still be *positioned on* the outer surface of the soft tissue and would not fulfill the requirement of "being shaped to seat below the first surface of the soft tissue." The rejection's assertion to the contrary simply defies the understanding of a person of ordinary skill. Indeed, by the rejection's logic, *a BAND-AID® bandage applied to the sole of a person's foot would satisfy the claim when the person is standing on the foot.* Yet by that same logic, the BAND-AID® bandage would not be seated below the soft tissue if the person were standing on their hands. The rejection's logic simply makes no sense and certainly falls well beyond any reasonable interpretation of the claims. Even when the bandage is positioned *under* the foot, the bandage is still *on, not below,* the foot surface. As the term is used in the claims and in accordance with the understanding of one of ordinary skill, a position "below" the soft tissue clearly indicates a *subcutaneous* position. As the term is used in the claims and in accordance with the understanding of one of ordinary skill, a position "below" the soft tissue clearly indicates a *subcutaneous* position. Nothing in Appellants' specification or within the common understanding of one skilled in the art would lead a person of ordinary skill to find that a structure, like suture retainer 540, shaped to be *seated on* the outer surface of the soft tissue and *in contact with the largest possible area of* that outer surface is a structure shaped to be positioned below that surface.

More specifically in regard to claims 10 and 13-17, no one skilled in the art would find a *frustoconical shaped, non-tissue contacting end* of the suture retainer 540 to be "a frustoconical end *shaped to bury into and seat below the first surface of the soft tissue*" as recited in the claims. Indeed, "to bury into" the first surface, the frustoconical end must make at least some contact with the first surface; yet even when the orientation of FIG. 26 is reversed, the rejection's frustoconical end is *never* in contact with the surface 98 of the soft tissue 54. If the frustoconical end is *never* in contact with the surface of the soft tissue, it is simply illogical to suggest that the end is somehow shaped *to bury into and seat below the surface of the soft tissue*. Again, nothing

in Appellants' specification or within the common understanding of one skilled in the art would lead one to adopt the rejection's proposed interpretation.

The rejection is based on a flawed interpretation of the "shaped to bury into and seat below the first surface of the soft tissue;" as such, Appellants submit that the rejection has failed to establish that claims 10 and 13-17 are rendered *prima facie* obvious by the combination of Wilk and Bonutti. Appellants respectfully urge the Board to reverse the rejection of those claims.

B. CLAIM 11 IS NOT OBVIOUS OVER BONUTTI AND WILK

Appellants fully incorporate into this section the legal authorities and arguments put forth in Section II.A above regarding the Section 103(a) rejection based on Bonutti and Wilk. Claim 11 depends from claim 10. As discussed herein, the Examiner has failed to establish a proper rejection under Section 103 of claim 10. Appellants submit that the Board should reverse the rejection of claim 11 for at least the reasons hereinbefore discussed with regard to claim 10. *See In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988) ("Dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious."). Claim 11 also recites that "the soft tissue is a meniscus." As discussed in Section I.B, the term "meniscus" simply does not appear in Bonutti; thus, Bonutti does not *expressly* disclose that an anchor may be used to engage a first surface of a meniscus on the first side of a defect. The addition of Wilk does not cure that deficiency. Thus, the proposed combination of references does not expressly arrive at the claimed invention.

Nor has the rejection provided the analysis or evidence necessary to show that the device resulting from the combination of Bonutti and Wilk is inherently capable of engaging a first surface of a meniscus. The Federal Circuit has emphasized that "[t]he fact that a certain result or characteristic *may* occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ 2d 1955, 1957 (Fed. Cir. 1993) (emphasis in original). Moreover, the Federal Circuit has said "[t]hat which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown." *Id.* (quoting *In re Spormann*, 363 F.2d 444, 448, 150 USPQ 449, 452 (CCPA 1966)). The burden is therefore on the examiner to provide the technical reasoning and extrinsic evidence necessary "to reasonably support the determination that the allegedly inherent

characteristic necessarily flows from the teachings of the applied prior art." MPEP § 2112.IV (quoting *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)) (emphasis in original). Here, the rejection has failed to put forth any reasoning or evidence to show that the device resulting from the combination of Bonutti and Wilk is *necessarily* capable of being used with meniscus.

As discussed above, the suture retainer 540 of Bonutti appears to extend or protrude some distance above or away from the surface 98 of the soft tissue 54. Appellants' specification highlights on page 5, lines 20-21 that "a protruding anchor may interfere with joint articulation." It is simply unclear from the combination of Bonutti and Wilk whether or not the suture retainer 540, as modified by the rejection, would interfere with joint articulation and therefore it is unclear whether the device resulting from the combination of Bonutti and Wilk is suitable for use with meniscus. Perhaps, as the rejection suggests, the resulting device *might* be used with meniscus; yet, given the fact that some protruding anchors interfere with joint articulation, it is equally possible that the resulting device *might not* be used with meniscus. Based on disclosures of Bonutti and Wilk, it is impossible to say that the resulting device is *necessarily* capable of being used with meniscus, and the rejection has simply not set forth the required extrinsic evidence or reasoning that makes "clear that the missing descriptive matter is necessarily present." *See In re Robertson*, 169 F.3d 743, 745, 49 USPQ 2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted). The rejection has therefore not established that the device resulting from the combination of Bonutti and Wilk is inherently capable of being used with meniscus.

Appellants therefore submit that the rejection has failed to show that proposed combination expressly or inherently arrives at the invention of claim 11. The rejection has simply not provided the factual basis for its rejection; as such, the rejection has failed to establish that claim 11 is rendered *prima facie* obvious by the combination of Wilk and Bonutti. Appellants respectfully urge the Board to reverse the rejection of that claim.

Moreover, given the Examiner's failure to articulate the basis of the rejection of claim 11, the Board's review represents the first meaningful substantive review of that claim. Should the Board decide that anything other than allowance of the claim is warranted, Appellants respectfully ask the Board to outline its position in a new ground of rejection so that Appellants can have an opportunity to adequately respond to what would be the first factually supported rejection of claim 11.

C. CLAIM 12 IS NOT OBVIOUS OVER BONUTTI AND WILK

Appellants fully incorporate into this section the legal authorities and arguments put forth in Section II.A above regarding the Section 103(a) rejection based on Bonutti and Wilk. Claim 12 depends from claim 10. As discussed herein, the Examiner has failed to establish a proper rejection under Section 103 of claim 10. Appellants submit that the Board should reverse the rejection of claim 12 for at least the reasons hereinbefore discussed with regard to claim 10. *See In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988) ("Dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious."). Claim 12 also recites that "proper seating of the device closes the defect without interfering with joint articulation." Neither Bonutti nor Wilk expressly disclose a device used in connection with a knee joint and neither reference contains a discussion of joint articulation. Nor has the rejection provided the analysis or evidence necessary to show that the device resulting from the combination of Bonutti and Wilk is inherently capable of properly seating such that the defect is closed without interfering with joint articulation.

The rejection has simply failed to put forth any reasoning or evidence to show that the suture retainer 540, as modified by the rejection, would be *necessarily* capable of seating such that the defect is closed without interfering with joint articulation. As shown in FIG. 26, the suture retainer 540 appears to extend or protrude some distance above or away from the surface 98 of the soft tissue 54. As discussed above, Appellants' specification highlights on page 5, lines 20-21 that "a protruding anchor may interfere with joint articulation." Perhaps, as the rejection suggests, proper seating of the resulting device *might* close a defect without interfering with joint articulation; yet given the fact that some protruding anchors interfere with joint articulation, it is equally possible that the resulting device *might not* close a defect without interfering with joint articulation. Based on the disclosures of Bonutti and Wilk, it is impossible to say that proper seating of the device resulting from a combination of those references *necessarily* closes a defect without interfering with joint articulation, and the rejection has simply not set forth the required extrinsic evidence or reasoning that makes "clear that the missing descriptive matter is necessarily present." *See In re Robertson*, 169 F.3d at 745, 49 USPQ 2d at 1950-51. The rejection has therefore not established that the device resulting from the combination of Bonutti and Wilk *inherently* closes a defect without interfering with joint articulation.

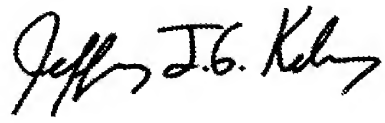
Appellants therefore submit that the rejection has failed to show that proposed combination expressly or inherently arrives at the invention of claim 12. The rejection has simply not provided the factual basis for its rejection; as such, the rejection has failed to establish that claim 12 is rendered *prima facie* obvious by the combination of Wilk and Bonutti. Appellants respectfully urge the Board to reverse the rejection of that claim.

Moreover, given the Examiner's failure to articulate the basis of the rejection of claim 12, the Board's review represents the first meaningful substantive review of that claim. Should the Board decide that anything other than allowance of the claim is warranted, Appellants respectfully ask the Board to outline its position in a new ground of rejection so that Appellants can have an opportunity to adequately respond to what would be the first factually supported rejection of claim 12.

III. CONCLUSION

In view of the arguments presented above, Appellants submit that the two grounds of rejection are erroneous. Appellants urge the Board to reverse the rejection of the pending claims and respectfully request action to that end.

Respectfully submitted,



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Jeffrey T.G. Kelsey
Attorney Reg. No. 63,696
11 South Meridian Street
Indianapolis, Indiana 46204-3535
Telephone: (317) 231-6412
Fax: (317) 231-7433

CLAIMS APPENDIX

Appellants submit the following list of claims involved in the appeal in accordance with 37 C.F.R. § 41.37(c)(1)(viii):

1. A device for repairing a defect in a soft tissue, comprising:

a first anchor for engaging a first surface of the soft tissue on a first side of the defect, the first anchor having a locking mechanism and a cannula defined therein, the cannula including a first lumen, the first anchor being shaped to seat below the first surface of the soft tissue;

a second anchor for engaging against a second side of the soft tissue on a second side of the defect; and

a suture adjustably connecting the second anchor to the first anchor, whereby tension on the suture pulls the second anchor toward the first anchor through a continuous range of distances, thereby pulling the first and second sides of the defect together to close the defect, and the locking mechanism locks the suture in place at any point along the suture,

wherein the second anchor has a hole and the suture connects the first anchor to the second anchor by passing through the first lumen of the cannula of the first anchor while traveling in a first direction, by passing through the hole of the second anchor, and by returning through the first lumen of the cannula of the first anchor while traveling in a second and opposite direction.

2. The device of claim 1 wherein the soft tissue is a meniscus.

3. The device of claim 2 whereby proper seating of the device closes the defect without interfering with joint articulation.

4. The device of claim 2 wherein the locking mechanism is configured to grip and hold the suture.

6. A device for repairing a defect in a soft tissue, comprising:

a first anchor for engaging a first surface of the soft tissue on a first side of the defect, the first anchor having a locking mechanism and a cannula defined therein, the cannula including a first lumen, the first anchor being shaped to seat below the first surface of the soft tissue;

a second anchor for engaging against a second surface of the soft tissue on a second side of the defect; and

a suture adjustably connecting the second anchor to the first anchor;

wherein the second anchor has a hole therethrough and the suture connects the first anchor to the second anchor by passing through the first lumen of the cannula of the first anchor while traveling in a first direction, by passing through the hole of the second anchor, and by returning through the first lumen of the cannula of the first anchor while traveling in a second and opposite direction and wherein tension on the suture pulls the second anchor toward the first anchor, thereby pulling the first and second sides of the defect together to close the defect, and the locking mechanism locks the suture in place.

7. The device of claim 6 wherein the soft tissue is a meniscus.

8. The device of claim 7 whereby proper seating of the device closes the defect without interfering with joint articulation.

9. The device of claim 7 wherein the locking mechanism is configured to grip and hold the suture.

10. A device for repairing a defect in a soft tissue, the device comprising:

a first anchor for engaging a first surface of the soft tissue on a first side of the defect, the first anchor having a locking mechanism and a single lumen defined therethough, the first anchor having a frustoconical end shaped to bury into and seat below the first surface of the soft tissue;

a second anchor for engaging a second surface of the soft tissue on a second side of the defect, the second anchor including at least one hole; and

a suture coupled to the first anchor and the second anchor, the suture passing through the lumen of the first anchor, passing through the at least one hole of the second anchor, and returning through the lumen of the first anchor, wherein tension on the suture pulls the second anchor toward the first anchor such that the first and second sides of the defect are pulled together and the locking mechanism locks the suture in place.

11. The device of claim 10, wherein the soft tissue is a meniscus.

12. The device of claim 11, whereby proper seating of the device closes the defect without interfering with joint articulation.

13. The device of claim 10, wherein the locking mechanism is configured to grip and hold the suture.

14. The device of claim 10, wherein the suture forms a loop with respect to the first anchor.

15. The device of claim 10, wherein the lumen of the first anchor includes a first opening defined in a first side of the first anchor and a second opening defined in a second side of the first anchor, the first opening being larger than the second opening.

16. The device of claim 10, wherein the lumen of the first anchor is tapered.

17. The device of claim 10, wherein the second anchor includes a first hole and a second hole, the suture passing through the first hole in a first direction and returning through the second hole in a direction opposite the first direction.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.